

POSITRON EMISSION TOMOGRAPHY

I. INTRODUCTION

Positron Emission Tomography or "PET" is a non-invasive diagnostic technology which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals which are injected into the body and whose interaction with body tissues and organs is able to be pictured through a computerized positron transaxial reconstruction tomography scanner. The radiopharmaceuticals are positron-emitting isotopes.

PET has existed since the late 1970's as a research technology. Currently, limited, but increasing uses are made for PET technology in diagnosing and assisting with treatment in certain neurological, psychiatric, cardiac and oncology patients.

II. DEFINITIONS

A. "Applicant" means the Facility that provides the PET service.

B. "Cyclotron" means a nuclear accelerator, which is used to generate the radiopharmaceuticals that are injected into a patient to enable computerized images to be generated through the use of a PET scanner to provide physiological and biochemical information about the patient. Cyclotrons are two types: Positive ion and negative ion.

C. "Facility" means acute care facility.

D. "Fixed PET" means a stationary PET service, which includes two major elements: A Cyclotron that produces the radiopharmaceuticals, and a PET scanner which includes a data acquisition system and a computer.

E. "HCA" means the West Virginia Health Care Authority.

F. "Mobile PET" – means a mobile unit that includes a data acquisition system and a computer. The radiopharmaceuticals are transported to the mobile unit from an existing Cyclotron. Mobile PET unit must be shared between two or more acute care facilities.

G. "PET Study or Scan" means the gathering of data during a single patient visit from which one or more images may be constructed of a single anatomical region of the patient's body.

III. NEED METHODOLOGY

A. FIXED PET UNITS

NEW SERVICE/ADDITIONAL EQUIPMENT

An Applicant proposing the acquisition of a Fixed PET unit must document that it has performed more than 950 procedures on a Mobile PET unit within the last twelve (12) month period and can project a total of 1,250 procedures annually on the Fixed PET unit.

An Applicant proposing the acquisition of an additional Fixed PET unit must document that each existing Fixed PET unit has performed 1,250 procedures annually. In addition, the Applicant must demonstrate it has performed a minimum of 950 procedures on a Mobile PET unit.

An exception to the quantitative need methodology may be granted if an Applicant can present clear and convincing evidence that approval of a new or additional Fixed PET unit is a superior alternative to the provision of Mobile PET services.

B. MOBILE PET UNIT

Facilities proposing the addition of Mobile PET services must address the following criteria:

1. The equipment must be on site at each Facility at least two (2) days per month.
2. The Applicant must identify:
 - a. each Facility involved with the shared equipment;
 - b. the equipment to be utilized;
 - c. a complete list of all persons and/or entities with an ownership interest in the equipment or an ownership interest in the entity that owns the equipment;
 - d. the fair market value of the equipment;
 - e. any capital expenditure to be made by the Applicant; and,
 - f. the proposed charges for the service by type of scan.

3. The Applicant must submit projected revenue and expense statements for the first three (3) years of operation of the Mobile PET services which include any allocation of Facility costs and other information as may be requested by the HCA.
4. The Applicant must disclose if, under its contract with the mobile vendor, there are any requirements for a minimum number of scans.

To assist in monitoring PET services, the Applicant will provide data to the HCA on an annual basis. That reporting will include, but not be limited to, the following:

1. Number of PET procedures performed;
2. Number of inpatient procedures performed (by type of procedure);
3. Number of outpatient procedures performed (by type of procedure);
4. Charges (gross charges, reimbursement received, breakdown by payors – Medicare, Medicaid, Other Governmental, Commercial, and Private Pay) for clinical scans;
5. Average charge per specific procedure;
6. Total days and hours per year of operation of the PET unit; and,
7. Any determinations made concerning more expensive or invasive procedures avoided as a result of the use of PET.

IV. QUALITY

The proposed Fixed PET/Mobile PET service must function as a component of a comprehensive diagnostic service. The Facility must have accessible the following modalities and capabilities on site or through contractual arrangements:

1. Computed Tomography - whole body;
2. Magnetic resonance imaging - brain and whole body;
3. Nuclear medicine - cardiac, SPECT;
4. Conventional radiography.

An Applicant proposing to provide Fixed PET/Mobile PET services must address the following quality related criteria in its application for a Certificate of Need:

1. The application must contain written assurances that the service will be offered in a physical environment that conforms to federal standards, manufacturer's specification, and licensing agencies' requirements. The following areas are to be addressed:
 - a. quality control and assurance of radiopharmaceuticals production of generator or cyclotron-produced agents;
 - b. quality control and assurance of PET tomograph and associated instrumentation;
 - c. radiation protection and shielding; and,
 - d. radioactive emissions to the environment.
2. The Applicant must affirm that the PET unit is registered with the West Virginia Bureau for Public Health Radiological Health Program for the proposed site, plans, and equipment before services begin.
3. The Applicant shall document access to a supply of cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceuticals production facility within an appropriate transport radius.
4. The Applicant must affirm that the U.S. Food and Drug Administration has certified the proposed PET equipment for clinical use.
5. The Applicant must document the PET training and experience of the operational staff. The following staff must be available to the Fixed PET/Mobile PET unit:
 - a. Safe operations of a Fixed PET/Mobile PET unit can be accomplished through a qualified physician being available for supervision. Qualifications for such a physician include:
 - Board certification in Diagnostic Radiology or Nuclear Medicine
 - State licensure to handle radionuclides
 - A minimum of 1,000 hours of cross-sectional imaging interpretation
 - A one-week PET fellowship
 - Twelve (12) hours of PET-specific CME every three (3) years
 - b. Qualified PET radiochemist or radiopharmacist personnel, available to the Facility during service hours, with at least one (1) year of

training and experience in the synthesis of short-lived positron emitting radiopharmaceuticals.

- c. Qualified engineering and physics personnel, available to the Facility during service hours, with training and experience in the operation and maintenance of the PET equipment.
 - d. Qualified radiation safety personnel, available to the Facility, with training and experience in the handling of short-lived positron emitting nuclides.
 - e. Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures.
 - f. Other appropriate personnel shall be available during service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radio-chemistry technicians.
- 6. The Applicant must require that the Mobile PET provider employ a full-time transportation manager, who will ensure that all DOT rules and regulations are being met.
 - 7. The Applicant must require that the provider be accredited by Joint Commission on Accreditation of Health Care Organizations.
 - 8. The Applicant must demonstrate how medical emergencies within the Fixed PET/Mobile PET unit will be managed in conformity with accepted medical practice.
 - 9. The Applicant must affirm that protocols based on national standards, will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed as well by other, less expensive, established modalities.
 - 10. The Applicant must have a referral system that includes a feedback mechanism for providing patient information to the referring physician.
 - 11. The Applicant must maintain current listings of appropriate PET procedures that may be clinically appropriate. The listing will be made available for use by referring physicians.

V. COST

Applicants shall demonstrate the financial feasibility of the proposal by providing an analysis of the cost-effectiveness of the proposed project to include:

1. A three (3) year projection of revenues and expenses for the project;
2. Evidence that sufficient capital is available to initiate and operate the proposed project;
3. Evidence that financing arrangements are reasonable and secure;
4. Documentation that all indigent persons needing the service can be served without jeopardizing the viability of the project;
5. Demonstration that the applicant is willing to participate in reasonable utilization management programs sponsored by peer review or managed care organizations; and,
6. That the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals as defined by the Authority.

VI. OTHER

The applicant must provide additional information, as may be requested by the Authority, regarding demographics data, financial data, and clinical data for patients receiving the service.